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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,664	10/18/2004	Michael A. Goetz	21121YP	4659

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EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
09/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,664	GOETZ ET AL.	
	Examiner	Art Unit	
	Paul W. Dickinson	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) 7-11 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☒ Claim(s) 3 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6 pages.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, Claims 1-6, with traverse, in the reply filed on 8/13/2007 is acknowledged. Applicant's further election of the potassium blocker paspalinine and the beta-adrenergic blocking agent timolol as the hypotensive agent is also acknowledged.

Claims 7-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Applicant's election with traverse in the reply filed on 8/13/2007 is acknowledged. The traversal is on the grounds that Groups I and II are related. Applicant argues that even though only one invention may be claimed in a single application, a reasonable number of species of the invention can be claimed if there is an allowable generic claim in the application. In addition, Applicant argues there is no additional burden on the part of the Examiner to conduct the prior art search. This is not found persuasive because the standard for restriction in a 35 U.S.C. 371 national stage application is a demonstration of lack of unity and not whether the number of disclosed species of the invention are reasonable. Search burden is also not a standard for restriction in 35 U.S.C. 371 national stage applications. See PCT Rule 13.1 and Rule 13.2. The restriction requirement mailed on 8/1/2007 clearly demonstrates lack of unity (see p 2,

second full paragraph starting with "The inventions listed..." through the following paragraph). The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6 are under consideration.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 3 cannot properly depend from itself. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

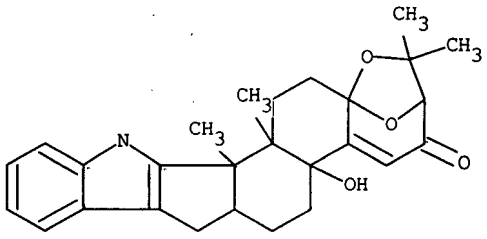
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "a therapeutically effective amount" in Claim 1 is vague and indefinite. The phrase "an effective amount" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. In re Fredericksen 213 F.2d 547, 102

USPQ 35 (CCPA 1954). Ocular hypertension and glaucoma have multiple causes and symptoms and it is unclear what element of the disease is being treated, and therefore what the therapeutically effective amount corresponds to. Examiner cites Schumer et al (Schumer et al, The Nerve of Glaucoma!, Arch Opthalmol., 1994, 112, 37-44; document submitted by Applicant) which teaches that hypertension and glaucoma have multiple causes. For example, increased intraocular pressure results from either increased production or decreased drainage of aqueous humor. In glaucoma research, increased intraocular pressure was long held to be a central cause. Some people with high intraocular pressure, however, never develop glaucoma (see p 28, col 1, ln 8 to col 2, ln 4). Numerous risk factors for glaucoma have been reported and there may be other causal variables involved (see p 28, col 2, ln 4-22). Examiner further cites http://www.cvr.org.au/glaucoma.htm, accessed 9/5/2007, which teaches that hypertension and glaucoma have multiple symptoms, including changes in the appearance of the optic disc, elevated intraocular pressure over 21 mm, 3 mm or more difference in intraocular pressure between the eyes, asymmetry or cupping between the 2 optic discs, myopia, and atrophy around the optic disc (see Ocular signs of glaucoma). In light of the multiple causes and symptoms associated with ocular hypertension and glaucoma, it is unclear what set of causes and/or symptoms "a therpauetically effective amount" corresponds to.

The term "paspalinine" in Claim 1 is vague and indefinite. Paspalinine is well known in the art to have the following structure:



(see Smith et al, Total Syntheses of (+)-Paspalicine and (+)-Paspalinine, J. Am. Chem. Soc. 1990, 112, 8197-8198; p 8197, col 1, ln 3-6; Scheme 1).

The disclosed structure of paspalinine in the instant application (see p 11 and Claim 1 of instant application) differs from the above structure. Reassigning a well known chemical name to a new structure without basis is repugnant to the art. One of skill in the art would not understand whether or not the claimed invention encompasses compounds having the commonly accepted structure of paspalinine or the structure disclosed by Applicant. Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." Multiform Desiccants Inc. v. Medzam Ltd., 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998).

Claims 2-6 depend from Claim 1, and are therefore also vague and indefinite

The phrase "formula I" in Claim 2 is vague and indefinite. It is unclear what formula I refers to.

The phrase "The method according to claim 3 wherein the topical formulation is a solution or suspension" in Claim 3 is vague and indefinite. Claim 3 depends from itself and it is unclear what method Applicant is referring to here.

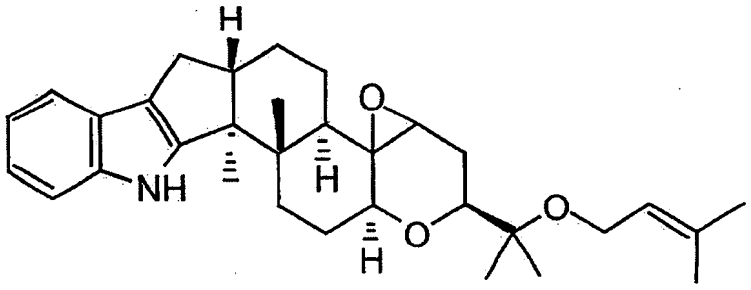
The phrase "prostaglandin derivative" in Claim 4 is vague and indefinite. The term "derivative" is indefinite because it is unclear how far one can deviate from the parent compound without the "derivative" being so far removed therefrom as to be a completely different compound.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Garcia et al (US 20010047025; document supplied by International Bureau). Garcia et al discloses a method for treating ocular hypertension by administration of a compound with the structure:



(see ¶ 159-165, 172, 178; Claims 1, 3). Garcia et al refers to this compound as Compound A (¶ 165) and the instant application refers to it as terpendole B (see Instant Claim 1). Garcia further discloses a topical formulation of compound A (see ¶ 32; Claim 2) wherein the topical formulation is a solution or suspension (see ¶ 35; Claim 4). Garcia et al further discloses administering a second active ingredient, concurrently or consecutively, wherein the second active ingredient is a β-adrenergic blocking agent (see ¶ 36; Claim 5). Garcia et al further discloses administration of the β-adrenergic blocking agent timolol (¶ 37; Claim 7). Garcia et al further discloses a topical formulation containing xanthan gum or gellan gum (¶ 113; Claim 17).

It is noted that Compound A (terpendole B) was discovered in the search for paspalinine.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

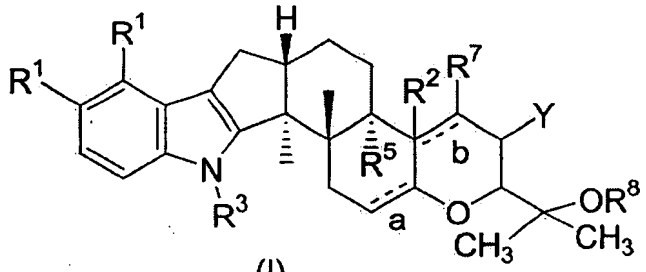
F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6548535. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain the following overlapping subject matter:

A method for treating ocular hypertension or glaucoma which comprises administering to a patient in need of such treatment a therapeutically effective amount of a compound with the structure:

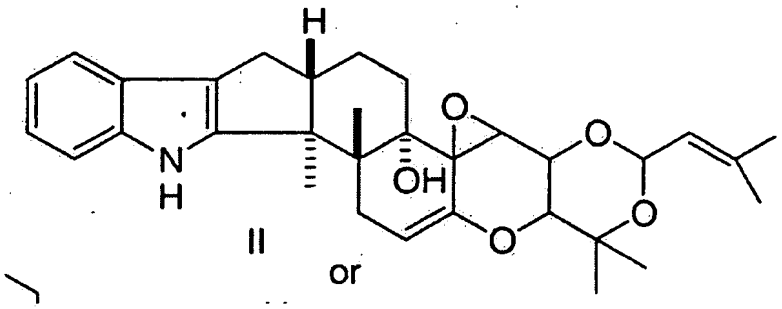


(I)

Claims 1-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application

No. 10533090. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain the following overlapping subject matter:

A method for treating ocular hypertension or glaucoma which comprises administering to a patient in need of such treatment a therapeutically effective amount of a compound with the structure:



II

or

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Gallagher et al, Paspalinine, A Tremorgenic Metabolite from Claviceps Paspali Stevens et Hall, Tetrahedron Letters, 1980, 21, 235-238.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul W Dickinson
Examiner
Art Unit 1609

September 5, 2007

Ardin H. Marschel 9/12/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER